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REMARKS/ARGUMENTS

The applicants have carefully studied the outstanding Office Action. The proposed claims have been amended to more distinctly and clearly recite the features of the present invention claimed over the prior art cited. The present amendment is intended to be fully responsive to all points of rejection raised by the Examiner, and is believed to place the application in condition for allowance. Continued examination, favorable reconsideration, and allowance of the application are respectfully requested.

Claims 1,3-7,9-11,15-21 and 23-28 are pending in the application, have been examined, and now stand rejected by the Examiner. By way of the present amendment, claims 1,3,4,6,9,10,15,16,19, 20 and 25 have been amended. Claims 11 and 18 have been cancelled.

Response to Examiners response to Applicants argument

With respect to the 112 rejections of claims 5, 6, 8 and 10, Examiner states that Applicant has not provided any structure in these claims, but instead relies on a functional limitation and that it is unclear how the apparatus is configured to perform this functional limitation. Examiner further recommends claiming the combination and configuration of elements that provide these functional limitations. Applicant's arguments are provided in the following pages.

Examiner states that "Applicant's asserting that none of the references teach that the target volume is on the symmetry axis beneath the skin surface" is not true and that Koziol discloses a full "lenticular ablation" (Figure 7), which necessary positions the target volume on the symmetry axis. Applicant respectfully disagrees. Koziol defines "lenticular ablation" as "removing corneal material via laser photoablation in the shape of an optical lens" and that "This ablation includes the **full surface** of the cornea" (page 8, line 4). That means Koziol's target could be on the symmetry axis, but only on the surface, not **beneath the surface**.

Claim Rejections - 35 USC §112

Prior claims 1,5,6,8,10, and 15 were rejected under 35 USC §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, Examiner states that it was unclear if the radiation impinge the surface at the symmetry axis. Applicant has amended claim 1 accordingly to recite that the radiation does not impinge the surface at the symmetry axis.

Regarding claims 1 and 9, Examiner states that Applicant does NOT provide any structure to support the functional limitation that "the reflective beam collector has convergence in one plan". Applicant recites that the support for structural limitation is to be found in Figs. 3A and 3D and paragraphs 0112, 0113 and 0138. For example, "The configuration shown in FIG. 3A provides convergence of the beam in **a plane** generally parallel to the tissue surface 26" (paragraph 0112).

Regarding claim 5, 6, 8 and 10, Examiner states that these recitations are intended uses of the invention and it is unclear how any of them necessarily modify the structure of the invention; and thus it is unclear how they modify the scope of the invention.

Applicant recites that claim 8 is a cancelled claim.

Applicant recites in respect to claims 5 that the structure illustrated in the embodiment of FIG 4A, where the redirected beam is a non-converging beam 41 (paragraph 0024). Such non-converging beam can be defined as a redirected beam having energy fluence that is less than or equal to the energy fluence of the input beam.

Applicant recites in respect to claims 6 that the modified structure is illustrated in the embodiment of FIG 4B in which the redirected, generally collimated beam 41 of FIG 4A is substituted by a convergent beam 47 to compensate for the scattering effect of the tissue, or in another embodiment the convergence can be more severe, resulting in a smaller and more intense target volume 46 (paragraph 0117). However, the focal point of the converging beam does not need to be within the target volume and may be outside the target volume as illustrated in FIG 4B and in the specification as originally submitted, "The convergence is normally directed to a region located far beyond the treatment zone" (paragraph 0110). For clarity, Applicant has amended claims 6 to recite "the focal point of such beam is located outside said target volume".

Applicant recites in respect to claims 10 that as illustrated in FIG 7A, the redirected beam has no focal point that overlaps with the target volume. Applicant has amended claims 10 to recite "said redirected beam is non-focused at said target volume".

Regarding Claims 6, 10 and 20, Examiner stated that it was unclear how the redirected radiation is "essentially non-focused" at the target volume is intended to limit the scope of the invention. Applicant recites that the meaning of "non-focused **at the target volume**" is that **if** the beam is focused, such focal point is not located within the target volume. Applicant farther recites, that the second point made by Examiner is incorrect. If a beam is being directed, it shouldn't be assumed focused with respect to its new direction. A directed beam, for example, could be collimated. Applicant has amended claim 6 to recite "the focal point of such beam is located outside said target volume". Applicant has amended claim 10 to recite "said redirected beam is non-focused at said target volume". Applicant has amended claim 20 to recite "said radiation is non-focused at said target volume".

Regarding claim 15, Examiner states that it's unclear what elements enable the convergence of the radiation independently in two planes. Applicant recites that such elements are shown for example in FIG. 3C. "FIG. 3C illustrates a perspective view of another preferred embodiment in which a cylindrical reflector 24A produces convergence in a plane parallel to surface 26, while the cylindrical reflector 25C produces convergence in a plane perpendicular to surface 26. Therefore, the convergence can be produced independently both in the plane parallel to the surface 26 and in the plane perpendicular to the surface 26" (paragraph 0114).

Applicant asserts that the limitation recited is not merely a functional limitation. Applicant respectfully submits that the present specification supports an interpretation where the phrase "configured to" denotes an actual state of configuration that fundamentally ties the level of the energy fluence of the redirected radiation to the physical characteristics of the apparatus. As a result, the claim language reaches well beyond merely describing a functional limitation, since the claims actively recite an actual state of configuration. The Examiner presented no evidence or reasoning why one of ordinary skill in the art would interpret the phrase "configured to" as merely denoting an intended use or functional limitation. Similarly, Applicant found no evidence or reasoning supporting this position in the claims, specification, prosecution history and extrinsic evidence. (As per *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005))

The applicant submits that the above recitations now provide the claims with a structural limitation.

Accordingly Applicant submits that the amended claims do comply with § 112 second paragraph and therefore requests withdrawal of this objection.

Claim Rejections - 35 USC §101

Prior claims 15-21 and 25 were rejected under 35 USC §101 as those claims allegedly do not affirmatively state the body of the claims that they are performed by a particular machine or elements and the steps do not result in a transformation of underlying subject matter from one state to another.

Applicants have amended claims 15-16 and 19, to recite particular elements.

Claim Rejections - 35 USC §103

Prior claims 1,3-7,9-11,15-21 and 23-28 were rejected under 35 USC §103(a) as allegedly unpatentable over Azar et al. (7066929) in combination with Koziol (5425727).

Regarding claims 1,3,9,17 and 23, Examiner states that Azar teaches performing selective photothermolisis on subcutaneous tissues using a plurality of beams that have energy insufficient to cause damage at the surface, but overlap within the tissue to cause damage (Abstract). Thus, the radiation at the surface is less than the maximum fluence of the radiation within the tissue. Examiner further states that Azar does NOT teach using Applicant's claimed structure.

Applicant has amended independent Claim 1 by reciting "a beam" instead of "radiation" and by reciting "said energy fluence of said radiation at said target volume is higher than said energy fluence of said radiation at said skin surface". Support for this amendment is to be found in Claim 1 as originally filed. Applicant submits that amended independent Claim 1 is novel over Azar and Koziol, or any combination thereof since as stated, in none of those references applies **a single beam** to the tissue.

Applicant has amended Claim 3 by reciting "a reflective element (25)" instead of "at least one reflective element" and "directed **beam**" instead "radiation". Applicant submits that amended Claim 3 is novel over Azar and Koziol, or any combination thereof since as stated, in none of those references uses **a single beam or a single reflective element.**

Applicant has amended independent Claim 9 by reciting "and wherein said radiation has a spectral band between 801nm and 1900nm. Applicant submits that this new limitation falls within the range stated in the disclosure (300nm to 11000nm), and does not,

therefore, constitute added subject matter. Applicant has further amended independent Claim 9 by reciting "said energy fluence of said radiation at said target volume is higher than said energy fluence of said radiation at said skin surface". Applicant submits that independent claim 9 as amended is novel over Azar and Koziol, or any combination thereof since, Azar teaches using radiation between 550-800 nm while Koziol teaches using radiation of 213nm (Fifth Harmonic Yag) and 532nm (Doubled frequency Yag).

Applicant has amended Claim 15 by reciting "said radiation has a spectral band between 801nm and 1900nm". Applicant submits that this new limitation falls within the range stated in the disclosure (300nm to 11000nm), and does not, therefore, constitute added subject matter. Applicant submits that independent claim 15 as amended is novel over Azar and Koziol, or any combination thereof since, Azar teaches using radiation between 550-800 nm while Koziol teaches using radiation of 213nm (5fth Harmonic Yag) and 532nm (frequency-doubled Yag).

Applicant submits that dependent claims 17 and 23 are dependent variously on independent claims 15 as amended, which the applicant claims as patentable.

Regarding claims 4, 11, 18 and 25, Azar teaches using radiation between 550-800 nm, which is well within Applicant's claimed range. Applicant has amended Claims 4 and 25 by reciting "a spectral band between **801**nm and **1900**nm". Claims 11 and 18 were canceled.

Applicant submits that amended Claims 4 and 25 are novel over Azar and Koziol, or any combination thereof since as stated, none of those references applies such spectral band.

Regarding claims 5, 19, 24 and 26-28, Examiner states that Koziol inherently teaches that the input radiation is greater than the redirected radiation, since the input radiation is divided. Examiner further states that "None of the elements have optical power". Applicant recites that all embodiments of Koziol's teaching include elements that have optical power in at least on plane. Optical Power, (also referred to as dioptric power, refractive power, focusing power, or convergence power) is the degree to which a lens, mirror, or other optical system converges or diverges light. For a mirror not having optical power means that such mirror must be flat. Koziol teaches that "each peripheral reflector has a curved reflective surface" (Abstract).

Regarding Claims 7 and 21, Examiner states that Azar teaches that the light incident on the skin is collimated by a collimating optic (82; Figure 6). However, it is NOT

the light incident on the skin that is collimated. The collimating optics in Azar's teaching is part of the sensing unit for sensing the temperature of the skin - "the sensing unit may include an optical sensor 81 and a collimating optical element 82 (page 10, lines 23-25). Examiner further states that "Although Koziol does not provide such an optic for the redirected light, it would have been obvious to provide one because doing so would reduce the interference of light beams/pulses with other beams/pulse redirected from the same reflector. This reduction in interference would result in more predictable and reproducible results." Applicant recites that collimated optics is not applicable to Koziol's device because the creation of incisions using Koziol's teaching necessities focusing the light into line focuses or point focuses.

Regarding claim 16, Examiner states that "it would have been obvious to also rotate during the method of Azar, because Azar also uses a scanner for providing forming a pattern in tissue". Applicant recites that Azar teaching does not mention a scanner or its use thereof. The rotation would have been **clearly unobvious**.

The References, and the Differences of the Present Claimed Invention Thereover

Following is a discussion of the references and the general novelty in the present claimed invention and its unobviousness over the references.

Applicant's claimed invention uses a single beam. Azar teaches a method and apparatus that uses a plurality of beams ("at least two pulsed beams") (Page 3, line 61).

In Applicant's claimed invention the beam is rotated, thus spreading the energy on the surface. Azar does not rotate, while the rotation of Koziol's teaching is aimed at ablating various annular shapes, rather than for reducing the energy fluence on the surface.

In Applicant's claimed invention, the radiation has convergence controllable independently in the plane parallel to the surface and in the plane perpendicular to the surface. Azar does not teach such features.

Applicant's claimed invention uses a single central reflector. **Koziol** teaches an apparatus and method for modifying curvature and refractive power of the cornea by creating incisions of various shapes on either the external surface of the cornea or onto intrastromal

area of the cornea. Koziol's structure is based on an even number of central reflectors "more than two and less than 16" (Page 5 lines 14-15).

In Applicant's claimed invention, the energy fluence on the surface is lower than the energy fluence on the symmetry axis beneath the surface. It is known in the art that cornea is a transparent member having a total thickness of 0.5–0.6 mm in the center and 0.6–0.8 mm at the periphery, while the stroma of the cornea is one of the middle layers of the cornea. The stroma is situated approximately 50μm below the surface of the cornea. Therefore it is clear that the light beams illustrated (Figs 2, 13 and 14) are converging towards the **surface or very close to the surface** but not towards a **single volume in the depth of the eye**. In Kaziol's teaching, the energy fluence on the surface is higher that the energy fluence on the symmetry axis in the depth of the eye.

In Applicant's claimed invention, the target volume is on the symmetry axis **beneath the surface**. Koziol's target, even in case of "lenticular ablation", could be on the symmetry axis, but could only be on the **surface**, NOT beneath the surface.

In Applicant's claimed invention, the focusing of the beam is not required and therefore the surface of the skin is spared. Koziol's teaching is not applicable to the skin because in contrast to cornea, which is a highly transparent member, the skin absorbs and scatters the light. Therefore, a focused beam of Koziol's device would ablate the surface of the skin.

Examiner states that "Koziol's radiation necessarily has a lower radiation at the tissue surface than the predetermined energy fluence, since the radiation with the predetermined fluence is divided before it reaches the surface and only converges once inside the tissue". Applicant recites that this is incorrect. Although the beam is divided before reaching the surface, it is also focused into a line or into a point on the surface or very close to the surface. The term "fluence" is defined as energy applied per unit area. Therefore, a beam focused into a line or a point has higher fluence than the predetermined energy fluence. Once inside the tissue the beam diverges rather than converges.

In Applicant's claimed invention the energy fluence on the symmetry axis in the depth is higher than the energy fluence on the surface. Koziol's teaches either creating incisions on the external surface of the cornea by focusing the beam on such external surface

or creating incisions onto intrastromal area of the cornea by focusing the beam on such intrastromal area. At the time the beam is focused on the surface or on the intrastromal area, the maximum energy is applied to the surface while any the energy fluence in a volume on the symmetry axis in the depth of the eye is significantly lower.

Examiner states that it would have been obvious to use the beam converter of Koziol with the method and device of Azar, because it would have enabled the input beam to be divided into more sub beams, which would have reduced the fluence at the surface. Applicant submits that the proposed combination would not be physically possible or operative because each reference teaches away from each other. Azar teaches using plurality of non focused beams and overlap them beneath the skin surface for treating a volume below the surface while sparing the surface, while Koziol teaches using focused beams for ablating the surface in multiple locations simultaneously. Moreover, even if the combination could be made physically, possible, dividing the input beam into more sub-beams would not reduce the fluence at the surface without reducing the fluence on each target.

Examiner further states that it also would have been advantageous to use the device of Koziol with the method of Azar. Because it would have require one light source, which would have reduces the number of elements relative to Azar's current apparatus. Applicant submits that the proposed combination would not be physically possible or operative. Koziol's teaching is not applicable to the skin because in contrast to cornea, which is a highly transparent member, the skin contains chromophores that would absorb the light and overheat. Therefore, a focused beam of Koziol's device would ablate the surface of the skin which is against the teaching of Azar.

Examiner further states that it would furthermore have been advantageous to use a device where the symmetry axis and the rotational axis are collinear, because it would have enabled the beams to recombine over a greater volume within the tissue, which would have again reduced the total energy at the surface and provided a larger treatment region. Applicant submits that the in Koziol's device the symmetry axis and the rotational axis are collinear, therefore, it's unclear how that feature reduced the total energy at the surface and provides a larger treatment region. Moreover, even if it would have provided a larger treatment region, such larger treatment region would be against the teaching of both Azar and Koziol because a larger treatment region would result in lower energy fluence at such treatment region and thus in a less effective treatment.

Examiner further states that that it also would have been obvious to use the converter of Koziol with the device/method of Azar, because the main point of Azar's invention is to provide a method that causes damage deep within the skin without causing epidermal damage. Applicant submits that the proposed combination would not be physically possible or operative. Koziol's converter splits the input beam into multiple sub-beams and focusing each of those sub-beams into separate point or line, thus creating multiple incisions of desired shapes symmetrically placed around the rotation axis. Applicant submits that without modifications, not taught in the prior art, Koziol's converter would not be effective in preventing the epidermal damage because, as opposed to the cornea which is transparent to light, the epidermis contains chromophores that would absorb the energy and overheat.

Applicant submits that the novel physical features claimed are also unobvious and hence patentable since they produce new and unexpected results over Azar and Koziol, or any combination thereof. Part of these new and unexpected results is the ability of Applicant's system to prevent epidermal damage without requiring active or passive cooling.

In summary, the Applicant submits that:
1. There is no justification in Azar and Koziol, or in any other prior art separate from applicant's disclosure, which suggests that these references be combined, much less in the manner proposed.
2. The proposed combination would not be physically possible or operative because each reference teaches away from each other.
3. Even if Azar and Koziol were to be combined in the manner proposed, the proposed combination would not show all of the novel physical features of the Claims as amended.
4. These novel physical features of the Claims as amended produce new and unexpected results and hence are unobvious and patentable over these references.

Conclusion

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Respectfully submitted

Alex Rapoport
Applicant